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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,752	11/30/2001	Eberhard Hildt	VOS-013-107070120	7711

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/890,752		HILDT ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Myron G. Hill		1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19- 51 is/are pending in the application.
- 4a) Of the above claim(s) 34- 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19- 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>22 December 2003</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 19- 51 are pending and claims 34- 51 are withdrawn from consideration.

Claims 19- 33 are under final rejection.

### ***Preliminary Amendment***

The Office acknowledges the clarification of the pending claims and the amended set supplied in response to the previous Office Action that presents the claims properly numbered.

### ***Sequence Requirements***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on as follows:

The paper sequence lists as filed do not contain a SEQ ID# 20 (this sequence is on the CRF).

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this Office Action will be held non-responsive.

### ***Drawings***

The drawing corrections, filed on 22 December 2003 have been accepted.

***Information Disclosure Statement***

A signed and initialed copy of IDS paper filed 22 December 2003 is enclosed.

***Claim Objections Withdrawn***

Claims 30 and 32 have been amended to be different in scope than 29 and 31, respectively. Claim 23 has been amended to spell out "LHBs".

All objections are withdrawn.

***Rejections Withdrawn***

***Rejections Maintained***

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 19- 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues the following: a) in the claims “cell permeability-mediating peptide” is definite, is defined, and is represented by at least one non-limiting example. b) “nucleic acid present in the protein envelope” is definite, the relationship is clear, and the claim has been amended to clarify the relationship. c) “derived” is definite, that the metes and bounds are clear as disclosed in the paragraph spanning pages 2 and 3. d) “Cells containing ...” is definite, and clear light of Example 1. e) the particles are isolated, and the claim has been amended to indicate such.

Applicant's arguments have been fully considered and found persuasive in part.

Items a, b, d), and e are clear because of amendment or explanation.

The rejection based on “derived” (item c)) is maintained because the passage describes virus protein and does not provide a limiting or definitional meaning of “derived”. While this passage may hint at what is meant by the term, the term “derived” is not used in this passage and the passage does not set forth the metes and bounds of “derived”.

The rejection of claim 33 on the term “Cells containing ...” (item d)) is withdrawn because of the amendment. However, see new rejection below.

Claims 19- 25, 27- 29, 31, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a written description rejection (WD).

The term "cell permeability-mediating peptide" is at issue in this rejection.

Applicant argues that MPEP 2163(I) states what satisfies WD, that the specification discloses SEQ ID #20, and SEQ #1(which contains one substitution of leucine to isoleucine, that the fusion protein of Figure 3 can differ by one or more amino acids, and that Examples 1 and 2 demonstrate the preparation of a particle according to the invention.

Applicant's arguments have been fully considered and not found persuasive.

The claims are drawn to a genus of peptides that are described by function. Applicant has shown SEQ ID #20 and a sequence that contains a single very conservative substitution of the sequence. Applicant has not disclosed a representative number of species to indicate possession of the full scope of the claimed genus, see MPEP 2163 II 3 (a) ii) For each claim drawn to a genus. The reference to a fusion protein that can differ from the disclosed sequence does not show what other peptides function as a "cell permeability-mediating peptide". Examples 1 and 2 do not state what sequence that is used for the "cell permeability-mediating peptide" but it is assumed to be the fusion protein, SEQ ID#1.

It is concluded that Applicant has not shown possession of the full range of peptides commensurate in scope of the claim to a genus.

***Claim Rejections - 35 USC § 102***

Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg (WO 97/24453).

Applicant argues that applicant does not necessarily agree with the examiner on the interpretation of the reference but note, in contrast to the claims, Rosenberg does not disclose a sequence encoding a virus specific packaging signal, and that Rosenberg does not provide working examples or details on how to perform experiments.

Applicant's arguments have been fully considered and found persuasive in part.

The rejection no longer applies to claim 33 because the cited art does not disclose the recited method.

It is clear from Rosenberg that the particles can be viral even though it is not explicitly stated, that the encapsidated nucleic acid must have a packaging signal in order to be included in the viral particle (page 14, lines 8- 15). The virus specific packaging signal must inherently be present in order to form the particle.

The argument concerning working examples is not persuasive because the claims are drawn to a product and the reference discloses a product that meets the limitations of the claims as discussed in the above and in the prior Office Action.

***Claim Rejections - 35 USC § 112***

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is "not expressing LHBs" refers to. It is not

Art Unit: 1648

clear if it refers to the cells or to the HBV genome. This is a new rejection based on the amendment.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Art Unit: 1648


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.



Myron G. Hill  
Patent Examiner  
April 30, 2004



JAMES HOUSEL 5/3/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600